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(54) Cryo-ablation catheter.

(57) The invention relates to a cryo-ablation catheter, comprising a tube-like basic body with a proximal and a distal end wherein at the distal end a closed head made of a thermally conductive material has been arranged, a pressure line extending in the basic body from close to the proximal end to close to the head comprising a restriction at its distal end, and a discharge channel extending from the head to the proximal end. The pressure line is made of a synthetic material with a, compared to metal, low modulus of elasticity and a high thermal resistance coefficient. At the proximal end the pressure line is connected with a fluid source under pressure and with cooling means for the purpose of cooling the fluid.

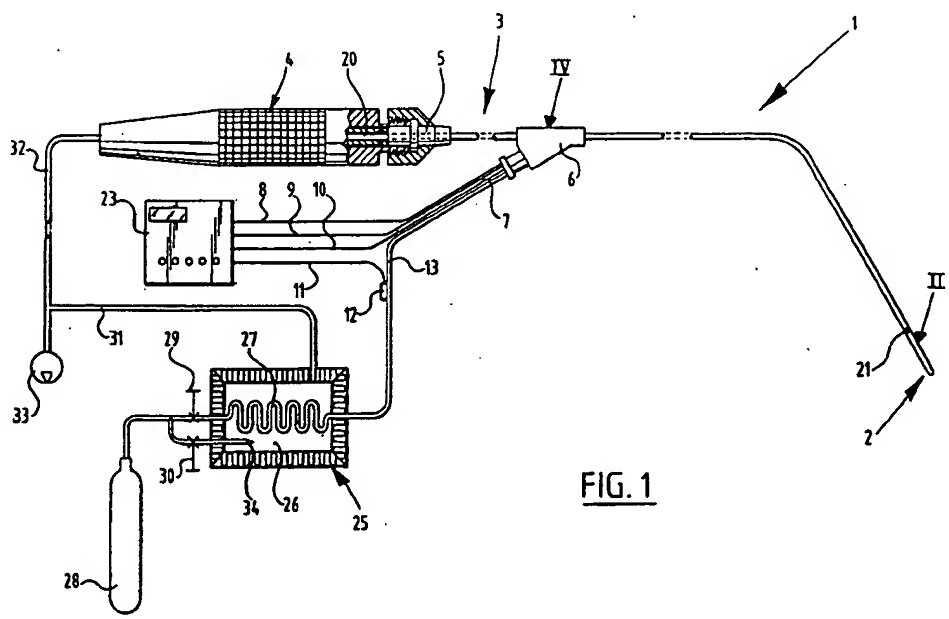

FIG. 1

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The invention relates to a cryo-ablation catheter as is known from the British patent application 2 226 497.

The catheter known from this publication comprises a tube-like basic body with a closed head, made of thermally conductive material, at a distal end. A thin stainless steel pressure line has been received in the basic body comprising a restriction at its end close to the head. A refrigerant under high pressure is supplied via the pressure line. Because of the restriction, the refrigerant expands in the head, whilst drawing heat from the surroundings. This cooling effect is known as the Joule-Thompson effect. With the head, thus cooled down to a very low temperature, ablation procedures can be carried out inside organs, for instance inside the heart of a patient.

With the known catheter the distal end of the pressure line is coiled helically and is exposed to the returning stream of expanded refrigerant. The helically shaped segment of the pressure line forms a heat exchanger, inside of which the supplied refrigerant is already pre-cooled. This is necessary to obtain a low temperature of the refrigerant, in order to achieve the very low temperature in the head following the expansion of the refrigerant.

The known catheter has the drawback that it is stiff, which makes it very difficult to carry out a non-traumatic procedure.

The object of the invention is to provide a catheter of the type mentioned above which is properly flexible and which also facilitates an appropriate, very low temperature of the head of the catheter.

This aim is achieved with the catheter as characterised in claim 1. It has become apparent that it is possible to supply already pre-cooled refrigerant into the pressure line close to the proximal end and yet guarantee a sufficiently low temperature of the head of the catheter, without necessitating heat exchange with the returning stream of expanded gas. By choosing a synthetic material with a high thermal resistance coefficient when making the pressure line, little heat transfer will take place across the wall of the pressure line. The pre-cooled refrigerant supplied into the pressure line close to the proximal end can therefore absorb only little heat during its transport to the head. Furthermore, the inside of the catheter is cooled by the returning stream of expanded gas, so that the supplied stream of refrigerant is, at the most, heated to only a very small degree. Where necessary, the catheter can be made to be very pliable as the material of which the pressure line has been made has, in relation to metal, a low modulus of elasticity, which in itself is known.

When employing the measure as set out in claim 2, the idea of partly embodying the pressure line as heat exchanger is abandoned completely and consequently also the additional pre-cooling effect of the returning stream of expanded gas is relinquished entirely. In spite of this it is possible to achieve a desired very low temperature of the catheter tip. By extending the pressure line and the discharge channel axially along their entire length, the basic body can have a small diameter which is conducive to treatment to be carried out with the catheter. To achieve an adequate discharge of the expanded refrigerant and consequently, to optimize the cooling effect at the tip, the discharge channel could be connected to exhaust means, so that a sufficient pressure difference at the restriction at the end of the pressure line can be maintained.

An advantageous embodiment is characterised in claim 3. Inside the lumen of the basic body, the pressure line is entirely surrounded by the stream of expanded refrigerant, so that minimal heat transfer via the wall of the catheter to the pressure line can take place.

To properly monitor the functioning of the catheter, the measure as set out in claim 4 is preferably employed. A thermistor may suitably be used as temperature sensor. Its signal lines can be made of very thin wires conducting electricity which will reduce the free cross-section of the lumen minimally.

The invention relates to and also provides a cryo-ablation catheter means comprising a catheter according to the invention of the type described above and wherein the pressure line is connected at the proximal end with a source of fluid under pressure and with cooling means for the purpose of cooling the fluid. The fluid under pressure may be a liquid as well as a gas. Inside the cooling means the refrigerant is pre-cooled to a desired low value, so that at the tip of the catheter a very low temperature can be achieved due to the Joule-Thomson effect already referred to. Inside the cooling means the fluid is cooled to a temperature of for instance -40 °C.

A suitable embodiment of this device is characterised in claim 6. When the catheter is relatively short and has a relatively large diameter, the discharged expanded refrigerant will have still such a low temperature at the proximal end of the discharge channel that it can be used to pre-cool the refrigerant in the pressure line in a suitable manner.

Another suitable, preferred embodiment is characterised in claim 7. Thus the fluid in the pressure line can be cooled considerably and very simply, wherein the cooling means need to take up only a relatively small volume. As the refrigerant under pressure is already present anyway, pre-cooling can be achieved in a very efficient manner.

The measure as set out in claim 8 is preferably employed. Because of this the temperature of the fluid to be supplied into the pressure line in the catheter can be monitored carefully, so that the desired cooling effect at the tip of the catheter can be achieved for certain.

The invention will be explained below with reference to a description of an example of an embodiment.

Fig. 1 illustrates schematically a cryo-ablation catheter means according to the invention.

Fig. 2 shows a cross-section of the distal end-section of the actual catheter in fig. 1 indicated with arrow II.

Fig. 3 shows a cross-section at arrows III-III in fig. 2.

Fig. 4 represents a partly cross-sectional view at the Y-piece indicated with arrow IV in fig. 1.

The catheter means in fig. 1 shows a catheter 1 according to the invention with a distal end 2 and a proximal end 3. The proximal end 3 carries a connecting member 5, by means of which the catheter has been received in a handle 4. The catheter 1 may be for single use, whereas the handle 4 is reusable.

The catheter 1 comprises a basic body 15 with at the distal end 2 a closed head 14 made of a thermally conductive material, for instance a metal.

The basic body 15 comprises one lumen 20 which serves as discharge channel in a manner to be explained later.

Inside the lumen 20 a pressure line 13 has been received, extending from the proximal end 3 of the catheter 1 to the distal end 2. By means of bonding agent 16 the pressure line 13 has been secured in the head 14. During the manufacturing process the distal end of the pressure line 13 is first secured in the head 14, after which the basic body 15 is pushed over the appropriate section of the head 14 and fixed to it.

The pressure line 13 comprises a restriction 17 at its distal end inside the head 14.

As fig. 4 illustrates, the pressure line 13 is led outside the basic body at a Y-piece 6 in the catheter 1. The pressure line 13 and the signal lines 8 - 10 still to be described, are led outside in the Y-piece 6 in a sealed manner so that the discharge channel formed by the lumen 20 remains separate.

Via the pressure line 13, refrigerant under high pressure can be conveyed to the distal end of the catheter. After passing the restriction 17 this refrigerant will expand, drawing heat from the surroundings. Because of this the head 14 will be cooled to a very low temperature.

The expanded gaseous fluid returns via the discharge channel 20 formed by the lumen, to the proximal end 3 of the catheter. Inside the handle 4 the discharge channel 20 is, sealed in an appropriate manner, connected to a line 32 which discharges the expanded fluid subsequently. A pump 33 may be received in this line 32, as is the case in the illustrated example of the embodiment, in order to ensure that also in case of very small diameters of the catheter 1, the expanded gas is discharged properly and that a sufficient pressure difference is maintained at the restriction 17 in order to achieve the desired cooling effect.

According to the invention the pressure line 13 is made of a synthetic material with a, compared to metal, low modulus of elasticity and high thermal resistance coefficients. The catheter 1 and in particular its distal end 2 can be made adequately pliable because of the low modulus of elasticity of the material of which the pressure line 13 has been made.

To achieve an adequate cooling effect in the head 14 of the catheter, the refrigerant is pre-cooled in the cooling means 25 prior to it being conveyed to the pressure line. The cooling means illustrated schematically in fig. 1 comprise an isolated cooling chamber 26, through which a tube 27 extends helically. The pressure line is connected to this tube 27. From a source of refrigerant , here depicted in the form of a pressure cylinder 28, a pressure fluid is supplied to the pressure line 27. By means of an adjustable valve 29, the required quantity can be set.

In front of the valve 29 a line branches off from the refrigerant line which , via a restriction 34, debouches in the cooling chamber 26. The quantity of fluid supplied into the cooling chamber 26 is set by means of the control valve 30. When passing the restriction 34 the refrigerant expands inside the chamber 26 and on doing so draws heat from the surroundings, that is to say from the refrigerant passing through the tube 27 which consequently will be cooled. The expanded fluid is extracted from the chamber 26 by the line 31, so that a sufficient pressure difference is maintained across the restriction.

As fig. 1 illustrates schematically, a temperature sensor 12 has been arranged at the proximal end of the pressure line, which , via a signal line 11, is connected with measuring equipment 23. Thus the temperature of the refrigerant, supplied into the proximal end of the pressure line 13, can be checked. On the basis of the measured temperature, the control valve 30 can be set. In another embodiment the control valve 30 can be operated by a control means on the basis of the temperature as measured with the sensor 12.

A temperature sensor 18 has also been received in the head 14 of the catheter. This sensor is connected with measuring equipment 20 via signal lines 9. With the aid of the temperature sensor 18, the temperature of the head 14 of the

catheter can be read off. The measured value can, if so desired, also be used to set the control valve 29. With another embodiment, operating the control valve 29 can be done automatically in accordance with the temperature measured in the head 14.

At the distal end the catheter is provided with an annular electrode which is also connected to measuring equipment 23 by means of a signal line 10. By means of the annular electrode 21 in combination with the electrically conductive head 24, measurements can be taken inside organs in order to determine the correct position for carrying out the ablation procedure.

The catheter means according to the invention is for instance used for ablating surface tissue inside the heart when treating certain cardiac arrhythmias. By cooling the tissue to a great extent, it will be frozen locally and be destroyed.

In the case of the illustrated catheter the reinforcing layer of the basic body made of braided metal wires forms a conductor for measuring signals, and the signal line 8 is therefore connected to this reinforcing layer at the Y-piece 6.

Due to the relatively high thermal resistance coefficient of the material of which the pressure line 13 has been made, the pre-cooled fluid will, at the most, absorb only little heat from the surroundings. Inside the basic body 15 of the catheter, the pressure line 13 extends through the central lumen. The expanded gas which is being discharged from the head 14, passes through this lumen. Initially this expanded gas has a very low temperature and is heated only very slightly in the head. The gas passing through the discharge channel 20 still has therefore a low temperature, so that consequently also no or only little warming up of the refrigerant supplied under pressure, will occur.

Although this has not been illustrated in fig. 1, the section of the pressure line 13 connected to the cooling means 25 will, as a rule, be provided with an isolation layer in order to prevent also here warming up of the pressure fluid.

It should be noted that in the figures only a conceivable embodiment is shown. Other embodiments are possible. The cooling means 25 for instance could be received in the handle 4. In that case the cooling line 13 can be surrounded by expanded exhaust fluid over almost its entire length, so that the temperature of the pressure fluid becomes properly controllable.

As has been mentioned before, with certain embodiments and certain settings of the fluid streams the expanded fluid flowing back can still have such a low temperature at the proximal end 3, that it can be used in the cooling means close to the proximal end to pre-cool the pressure fluid.

All these conceivable variants are considered to be included in the invention.

Claims

1. Cryo-ablation catheter, comprising a tube-like basic body with a proximal and a distal end, wherein at the distal end a closed head made of a thermally conductive material has been arranged, a pressure line extending in the basic body from close to the proximal end to close to the head comprising a restriction at its distal end, and a discharge channel extending from the head to the proximal end, wherein the pressure line is made of a synthetic material with a, compared to metal, low modulus of elasticity and a high thermal resistance coefficient.

2. Catheter as claimed in claim 1, wherein the pressure line and the discharge channel extend axially over their entire length in the basic body.

3. Catheter as claimed in claim 1 or 2, wherein the discharge channel is formed by a lumen of the basic body and the pressure line is a separate line, received, with an interstice, in this lumen.

4. Catheter as claimed in one of the previous claims, wherein a temperature sensor has been arranged in the head and of which signal lines extend through the discharge channel to the proximal end of the catheter.

5. Cryo-ablation catheter means comprising a catheter as claimed in one of the previous claims, wherein the pressure line is, at the proximal end, connected with a fluid source under pressure and with cooling means for the purpose of cooling the fluid.

6. Means as claimed in claim 5, wherein the cooling means comprise a heat exchanger which is connected to the pressure line on one side and to the discharge channel on the other side.

7. Means as claimed in claim 5 or 6, wherein the cooling means comprise an expansion-cooler in which part of the fluid under pressure expands whilst drawing heat from the remainder of the fluid.

8. Means as claimed in one of the claims 5-7, wherein a temperature sensor has been arranged at the proximal end of the pressure line.

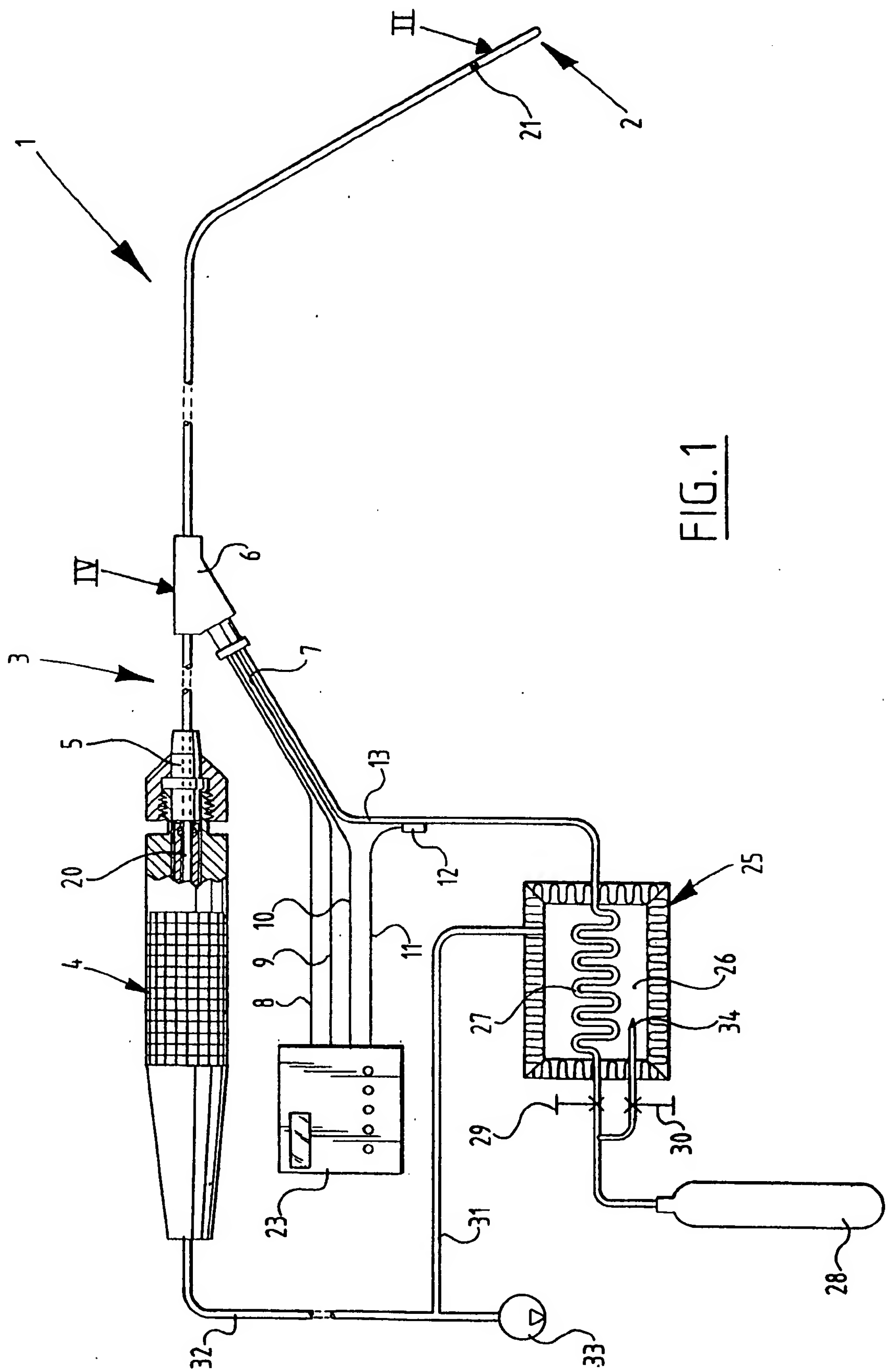

FIG. 1

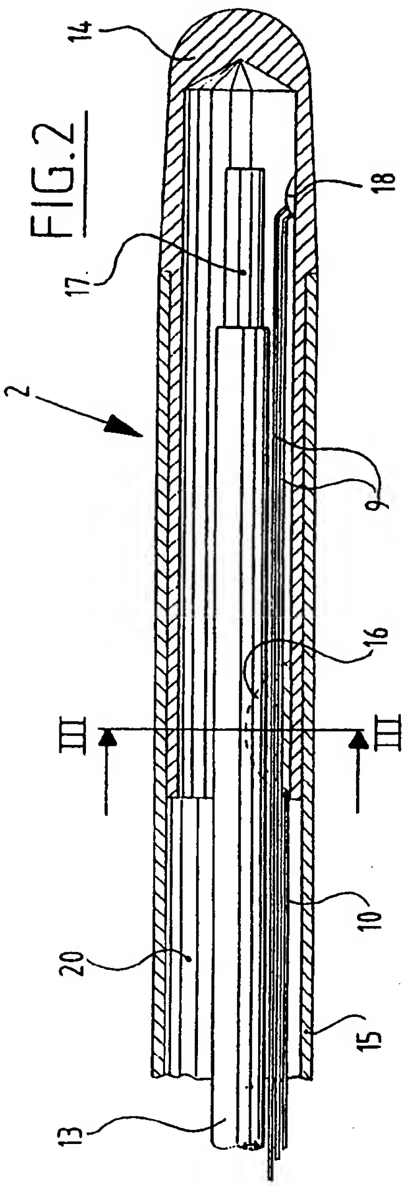

FIG.2

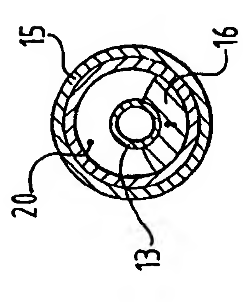

FIG.3

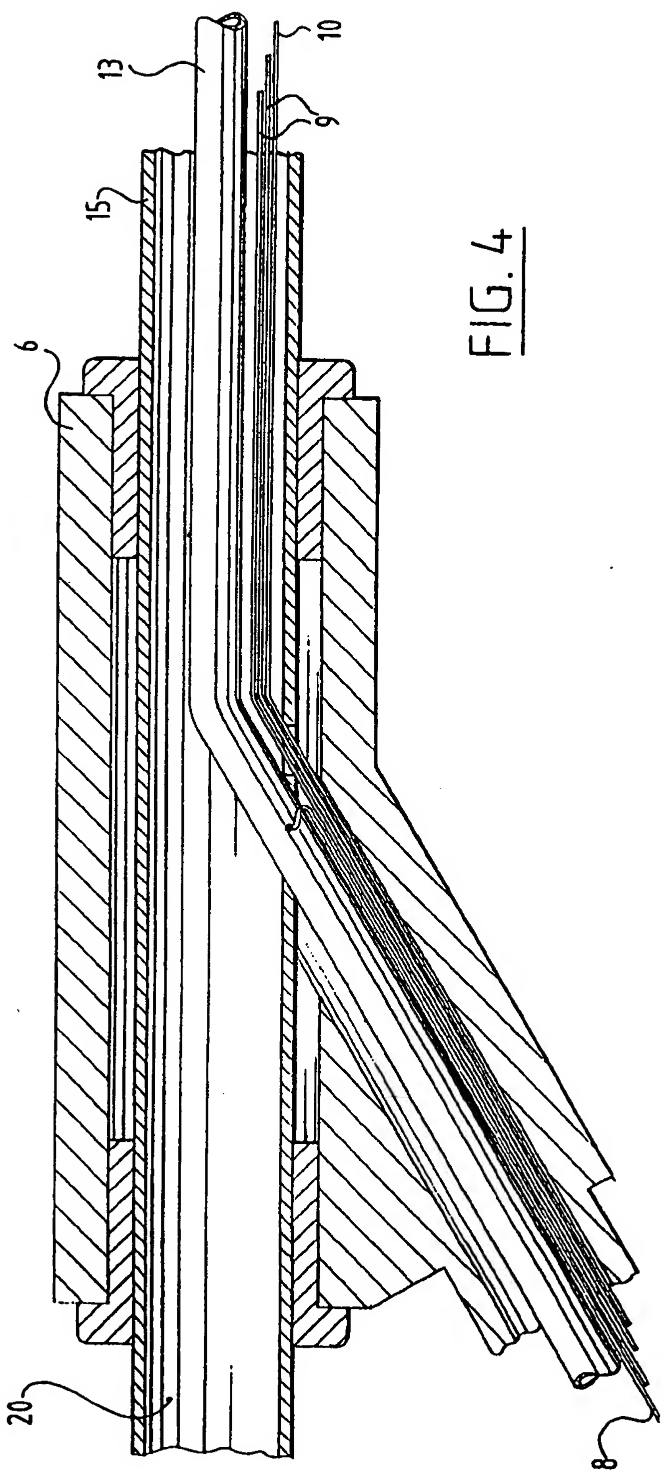

FIG.4

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EUROPEAN SEARCH REPORT

Application Number
EP 94 20 2749

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X Y	DE-A-23 32 513 (OKADA) * claims 1-5; figure 1 * * page 9, paragraph 3 * ---	1-3,5 4,6-8	A61B17/36
Y	DE-B-14 66 790 (CVI) * claims 1,10; figure 1 * ---	4,6,7	
Y	EP-A-0 395 307 (CRYO INSTRUMENTS) * column 7, line 18 - line 34; figure 1 * ---	8	
A	EP-A-0 437 377 (FERN) * abstract; figure 1 * ---	1	
A	DE-A-24 35 443 (FRIGITRONICS) * page 3, line 12 - line 14; figures 1,2 * ---	1	
A	FR-A-1 605 386 (BALKANSKI) * page 2, line 27 - page 3, line 30; figure 1 * ---	5-7	
A,D	GB-A-2 226 497 (SPEMBLY) * abstract; figures 1,2 * -----	1	TECHNICAL FIELDS SEARCHED (Int.Cl.6) A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	25 January 1995	Moers, R

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